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I hereby certify that this correspondence, including recited attachments, is being electronically transmitted to the Commissioner for Patents in the United States Patent and Trademark Office on the date below:

Date: June 7, 2010 Name: Richard E. Stanley, Jr. Signature: /Richard E. Stanley, Jr./ Reg. No. 45,662

Our Case No. 8627-1391
Client Ref. No. PA-5511-PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David G. Burton et al.

Serial No.: 10/593,376

Filing Date: July 9, 2007

For: MEDICAL BALLOON WITH ENLARGED TRANSITIONAL RADII

Examiner: Brian J. Graham

Group Art Unit No.: 3734

Confirmation No.: 8852

DECLARATION OF DAVID G. BURTON

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Now comes David G. Burton, who declares and states:

1. I live at 6524 E. Everett Arnold Dr., Bloomington, IN 47408. I have been employed by Cook Inc. for 12 years, and have been responsible for product development during my employment with Cook Inc. I am currently employed by Cook Inc. as a Sr. Engineer and work as part of the balloons and stents team. I am one of the named inventors of the above-identified patent application.

2. It is my understanding that the Examiner has rejected at least claims 1 and 22 in the above-identified patent application as being obvious in view of U.S. Patent Pub. No. 2003/0139762 ("Lee") and U.S. Patent No. 5,797,878 ("Bleam"). Based on my review of Lee and Bleam, and my personal experience, I offer the following opinions on the patentability of claims 1 and 22.

3. Lee relates to a method of making an angioplasty balloon. Lee claims that an advantage of the manufacturing method is that low profile and flexibility are achieved. (¶ [0027], line 9). Specifically, Lee's manufacturing method involves inserting an inner tube 106 through a shortened outer tube 102 to form a slug 100, as shown in Figure 2. (¶ [0025]). The slug 100 is then placed in a mold and heated and pressurized to form a balloon. (¶ [0025]). In the finished balloon, the shortened outer tube 102 forms the working length 44, and the inner tube 106 forms the proximal and distal tapers 48, 50. (¶ [0025], lines 13-17). As a result, less tube material is provided to the tapers 48, 50 than to the working length 44. (¶ [0027], lines 1-3).

4. By contrast, my invention relates to a medical balloon with enlarged radii at the working length-to-taper transition and the taper-to-neck transition. The enlarged radii provide smooth transitions from the working length to the taper and from the taper to the neck. As a result of the smooth transitions, lower forces are required to withdraw the balloon catheter through a delivery sheath or other conduit. (¶ [0044]). This advantage solves a number of potential problems. Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to pull back through a conduit after use. This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]). The claimed balloon catheter may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon. (¶ [0044]).

5. However, Lee does not relate to the balloon profile that I have developed. As explained above, Lee's balloon has tapers with a thinner wall thickness than the working length. By contrast, my invention relates to enlarged radii at the transitions between the working length and the tapers, and the transitions between the tapers and the necks. Not only is Lee related to an entirely different geometry than my invention, but Lee does not even mention the transitions between the tapers and the working length and the necks. Since Lee does not even refer to the relevant transitions, Lee also fails to specify any of the specific radii that I discovered for the transitions.

6. While Bleam generally recognizes the desirability of minimizing cross and recross forces (col. 2:31-34), Bleam solves this problem in a different way than my

invention does. The solution offered by Bleam is to change the angle α of the taper to make the tapered portions of the balloon more tapered. (Col. 5:53-55; 5:62-6:6). Bleam's preferred taper angle α is between 7° and 20°, 9° and 12°, or 10° and 11°. (Col. 6:52-56). However, this is not the solution that I developed. Instead, as noted above, my invention relates to a balloon where the radii at the transitions between the working length and the taper and between the taper and the neck region are enlarged—irrespective of the angle of the taper. Like Lee, Bleam does not mention the transitions that my invention relates to. Because Bleam doesn't mention the relevant transitions, Bleam also does not specify any dimensions for the transitions, much less the specific radii that I discovered.

7. In addition to the fact that the written descriptions of Lee and Bleam do not disclose anything about the transitions between the tapers and the working length and the necks, the figures of Lee and Bleam do not provide a suggestion to achieve my invention. As noted in the specification of my application, the transitions of an inflated balloon may actually look smooth; however when the balloon is deflated, the differences are significant. (¶ [0047]).

8. I state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements are the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

David G. Burton